

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (emphasis added).

Claims 1, 10-16, 18

Applicants respectfully traverse this rejection.

Claim 1 claims, among other elements, a method for anastomosis comprising “forming an incision in [a] target vessel; placing incision tensioners within the incision in the target vessel; tensioning the incision in the target vessel with the incision tensioners; and grafting the graft vessel to the target vessel while the incision is tensioned.” An incision is formed in a hollow target vessel, such as a coronary artery, as part of an anastomosis procedure. (*e.g.*, Figure 2; page 4). Anastomosis refers to a connection between two hollow anatomical structures, such as blood vessels. Incision tensioners are then placed into the incision in the target vessel. An incision tensioner is a structure such as identified in the specification in Figures 11-13 that engages the edges of an incision. Those incision tensioners then tension the incision in the target vessel. “The incision is tensioned when the incision is pulled taut.” (page 10, line 6). Then, a graft vessel is grafted to the target vessel, while the incision in the target vessel is pulled taut.

In contrast, U.S. Pat. No. 6,099,553 to Hart et. al. (“Hart”) neither discloses nor suggests even one of the four elements of claim 1. First, the only vessel disclosed in Hart is a vessel 32, reached through an incision 30 in the skin. (*e.g.*, Figure 1; column 5, lines 25-30). Hart neither discloses nor suggests making an incision in a target vessel. Rather, Hart only teaches making an incision in the patient’s skin to gain access to an intact vessel. An incision

in the patient's skin to gain access to an intact vessel is significantly different from an incision in a vessel itself. Indeed, Hart teaches away from making an incision in the vessel 32, because Hart teaches the use of suture to "occlude body conduits such as a vessel 32." (column 5, lines 29-30) (emphasis added). Occlusion restricts or terminates flow of bodily fluid through a vessel, while in contrast making an incision in a vessel allows fluid to flow through that incision.

Second, because Hart neither teaches nor suggests forming an incision in a target vessel, Hart necessarily cannot teach or suggest placing an incision tensioner or anything else within an incision in a target vessel. The Office Action erroneously identifies the suture clinch 10 of Hart as an incision tensioner. The clinch 10 is used to hold and tension suture, not an incision in a target vessel, nor any other bodily structure. Indeed, Figure 1 of Hart shows the clinch 10 spaced apart from both the vessel 32 and the incision 30 in the skin of the patient; it does not engage tissue at all. As shown in Figure 1 of Hart, the clinch 10 merely holds and tensions suture that is wrapped around the exterior of an intact vessel with no incision therein. Even if the clinch 10 were to be considered an incision tensioner, which Applicants do not admit, it is not placed "within [an] incision in the target vessel," as required by claim 1. Indeed, the clinch 10 is not even placed within the incision 30 in the skin of the patient.

Third, because Hart neither teaches nor suggests forming an incision in a target vessel, Hart necessarily cannot teach or suggest tensioning an incision in a target vessel with an incision tensioner or any other structure or mechanism. As stated above, the Office Action erroneously identifies the suture clinch 10 as an incision tensioner, when instead the clinch 10 holds and tensions suture. Further, Hart discloses no structure or method for pulling taut any incision at all, even the incision 30 in the skin of the patient.

Fourth, nowhere in Hart is a graft vessel disclosed or suggested. Thus, Hart necessarily cannot disclose grafting a graft vessel to the target vessel, much less while an incision in the graft vessel is tensioned. Hart is directed to a method of occluding a vessel, and thereby teaches away from a method for anastomosis, which involves creating a connection between vessels. The fact that the Office Action affirmatively links the target vessel to reference number 32 of Hart, and does not link the graft vessel to any reference number of Hart, confirms that Hart discloses no graft vessel.

Because Hart neither teaches nor suggests each and every element claimed in claim 1, Applicants consequently believe claim 1 is in condition for allowance. The Examiner has admitted on the record, in the Office Action of January 30, 2003, that claim 1 is generic. Thus, were claim 1 to be allowed, Applicants request allowance as to all species.

Claims 10-16 and 18 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III). With regard to claims 10-11, Hart does not disclose or suggest forming an incision in a target vessel, as described above, and therefore necessarily cannot disclose or suggest tensioning an incision in a target vessel to a predetermined length. Further, Hart does not disclose tensioning any incision in any tissue of a patient to a predetermined length. With regard to claims 13-14, Hart neither discloses nor suggests incision tensioners that are clips having tines. Instead, the items identified in the Office Action as the "first tine (54)" and "second tine (63)" are merely components of the clinch 10, which as stated above is not an incision tensioner. With regard to claims 15-16 and 18, the first tine 54 and second tine 63 are part of the clinch 10, as described above, and Hart does not disclose a graft vessel or any contact between the first tine 54 and/or second tine 63 and a graft vessel or target vessel, much less the "capture" of a graft vessel and a target vessel by the first tine 54 and/or the second tine 63.. Further, Hart neither discloses nor suggests tensioning an incision in the target vessel to allow a geometry of that

incision to remain constant during an anastomosis procedure; indeed, Hart does not disclose or suggest an anastomosis procedure at all.

35 U.S.C. §103

MPEP 706.02(j) states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 1438 (Fed. Cir. 1991) (emphasis added).

Claim 12

Applicants respectfully traverse this rejection.

Initially, Applicants note that claim 12 depends indirectly from claim 1, which is believed to be in condition for allowance; as a result, claim 12 is also believed to be in condition for allowance, under MPEP 608.01(n)(III).

The discussion above with regard to independent claim 1 is equally applicable here. Hart does not teach forming an incision in a target vessel or applying a predetermined force to that incision, via incision tensioners or any other mechanisms. Although Hart teaches applying a force to a suture, the claimed invention does not claim suture or suture tensioning. Hart discloses nothing with regard to a predetermined force that can be applied to an incision in a target vessel, and thus discloses nothing that can be modified to obtain the range of forces claimed in claim 12.

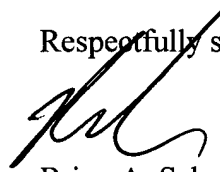
Applicants are confused by the statement that "such a modification would have involved a mere change in the size or shape of a component." Claim 12 is a method claim, and claims a force to be applied to the incision tensioners without claiming structure for applying such a force. As a result, there is no claimed "component" for exerting force, and therefore no "component" to be changed in size or shape as compared to Hart.

Because Hart neither teaches nor suggests all of the limitations of claim 12, Applicants believe claim 12 to be in condition for allowance.

REQUEST FOR ALLOWANCE

Allowance of the pending claims, as to all species, is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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